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TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.
DEG-10002/29

Application Of: Gillespie

Serial No.	Filing Date	Examiner	Group Art Unit
09/852,519	May 10, 2001	S. Sharareh	1617

Invention: MORE EASILY VISUALIZED PUNCTUM PLUG CONFIGURATIONS

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on: December 12, 2003

Applicant is a small entity under 37 CFR 1.9 and 1.27.

A verified statement of small entity status under 37 CFR 1.27:

- is enclosed.
- has already been filed in this application.

The fee for filing this Appeal Brief is: \$165.00

- A check in the amount of the fee is enclosed.
- The Director has already been authorized to charge fees in this application to a Deposit Account.
- The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 07-1180

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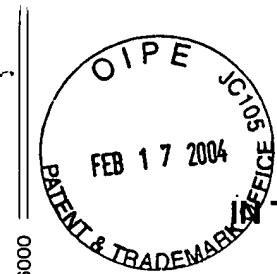
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES**

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In re application of: Gillespie

Serial No.: 09/852,519

Group No.: 1617

Filed: May 10, 2001

Examiner: S. Sharareh

For: MORE EASILY VISUALIZED PUNCTUM PLUG CONFIGURATIONS

APPELLANT'S APPEAL BRIEF

Mail Stop Appeal Brief
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. Real Party in Interest

The real party and interest in this case is Mr. Donald Gillespie, Applicant and Appellant.

II. Related Appeals and Interferences

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

The present application was filed with 21 claims. Claims 9-21 were canceled as the result of a restriction requirement. Claims 1-8 are pending and under appeal.

**IV. Status of Amendments Filed Subsequent
Final Rejection**

An after-final amendment was previously filed to cancel withdrawn claims 9-21. A further after-final amendment is filed herewith to amend claim 8 pursuant to 35 USC §112, second paragraph.

V. Concise Summary of the Invention

This invention resides in a punctum plug which is more easily visualized when positioned within a punctal canal of a recipient. Broadly, a plug according to the invention includes a body having an outwardly exposed surface when properly positioned, and a substance causing at least the outwardly exposed surface to contrast with surrounding tissue, such that the use of the substance causes the plug to be more easily visualized than if the substance were not present (Specification, page 2, lines 8-13). The rest of the plug body may be composed of any suitable material, including those presently used in the manufacture of such devices (Specification, page 2, lines 13-15).

The substance, which may be disposed on the outwardly exposed surface or within the body of the plug, may include a saturated coloration, or may be phosphorescent, fluorescent or otherwise operative to reflect or re-radiate light to assist in visualization. For example, the substance may include an organic or inorganic phosphor or fluorescent material, reflective beads, quantum dots, a dye or pigment (Specification, page 2, lines 16-20). Such reflection or re-radiation may occur at the same or different wavelength(s) compared to the illumination wavelength(s), whether or not either or both are within the visible part of the spectrum (Specification, page 2, line 20 to page 3, line 2).

If outside the visible region, a detector may be employed according to the invention for detecting the radiated light. A system for determining whether or not a punctum plug is positioned within the punctal canal of a person's eye is also enclosed, including at least one optical element permitting the eye to view itself, to be viewed by the other eye, or by a second person (Specification, page 3, lines 3-7).

**VI. Concise Statement of Issues Presented
For Review**

1. Are claims 1-4 and 6 anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 5,300,200 to L'Esperance?
2. Are claims 1-8 unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 4,959,048 to Seder et al. or U.S. Patent No. 3,949,750 to Freeman in view U.S. Patent No. 5,178,635 to Gwon et al.?

**VII. Grouping of Claims for Each Ground of
Rejection Which Appellant Contends**

Appellant believes the following groups of claims represent patentably distinct inventions which should be given independent consideration on appeal:

Group I: Claims 1-4, wherein claims 2-4 stand or fall with claim 1;

Group II: Claims 5-7, wherein claims 6-7 stand or fall with claim 5; and

Group III: Claim 8.

VIII. Argument

A. Group I - Claims 1-4, wherein claims 2-4 stand or fall with claim 1.

Claim 1 stands rejected under 35 U.S.C. §102(b) by L'Esperance, Jr., U.S. Patent No. 5,300,020.

The invention of this patent is directed to a surgically implantable device for controlled drainage flow of aqueous fluid from the anterior chamber of the eye into nearby subconjunctival space, with the goal being "relief of a glaucomatous condition of excessive pressure within the eye." ('020 patent, Abstract).

The device includes a provision for controlling the rate of aqueous flow so as to assure against anterior-chamber collapse, thus avoiding irreparable damage which might otherwise result to the corneal endothelium, to the iris, or to the lens of the eye.

It should be clear to the Board that the Examiner is misinterpreting the L'Esperance reference, and applying its "teachings" inappropriately. Although this reference mentions the use of photon, heat, or other energy absorbing compounds (dyes or chromophores), it is for the purpose of adjusting fluid flow and not for visualization. Anticipation may be established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention.

RCA Corp. v. Applied Digital Data Systems, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Moreover, anticipation requires the presence of all elements of a claimed invention as arranged in the claim, such that a disclosure "that 'almost' meets that standard does not 'anticipate'." Connell v. Sears, Roebuck Co., 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Accordingly, L'Esperance does not "anticipate the limitations of the instant claims," as the Examiner suggests.

Claim 1 also stands rejected under 35 USC §103(a) over Sedar et al., U.S. Patent No. 4,959,048, or Freeman, U.S. Patent No. 3,949,750, in view of Gwon et al., U.S. Patent No. 5,178,635. Sedar resides in a lacrimal duct occluder, having "an outwardly exposed surface," but that is about the only similarity whatsoever to the instant invention. Freeman is directed to a punctum plug and method for

treating keratoconjunctivitis sicca (dry eye) and other ophthalmic ailments. Again, Freeman includes “an outwardly exposed surface,” *but this is of no consequence relative to Appellant’s invention.* All “plugs” have an outwardly exposed surface; so do wine corks. But unless such devices have the rest of Appellant’s limitations *in combination, prima facie* obviousness is precluded.

Gwon et al. resides in a method for determining an amount of medication in an implantable device. It has nothing to do with punctum plugs in particular or plugs in general, but rather, uses a particular shape in the form of an annulus. Despite the Examiner’s argument that “Gwon is merely used to show that suitable dyes and fluorescent traces have been used in the art as a means for improving visualization and ophthalmic devices,” there is no teaching or suggestion *from the prior art* to support the Examiner’s position. In rejecting claims under 35 U.S.C. §103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. See In Re Fine, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner is expected to make the factual determinations set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 5569, 467 (1966), and to provide a reason why one having ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 293, 227 USPQ 657,664 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986); ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of presenting a prima facie case of obviousness. Note In Re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

B. Group II - Claims 5-7, wherein claims 6-7 stand or fall with claim 5.

Claim 5 stands rejected under 35 USC §103(a) over Sedar et al., U.S. Patent No. 4,959,048, or Freeman, U.S. Patent No. 3,949,750, in view of Gwon et al., U.S. Patent No. 5,178,635. Claim 5 adds to claim 1 the limitation of a punctum plug which is illuminated with light at an illumination wavelength, and wherein the substance generates radiated light at a wavelength other than the

illumination wavelength. In rejecting this group of claims, the Examiner primarily relies on the Gwon patent and, more particularly, col. 5, lines 30-50. But the Board will see that these passages do not apply to Appellant's invention. The device 10 of Gwon may be placed with an impervious layer 26 applied "so that an active agent is released from a side adjacent from the sclera only, thereby decreasing systemic drug absorption through the conjunctival blood vessels ... In combination with any one of the hereinabove-referenced active agents, the subconjunctival ocular insert 10, in accordance with the present invention, may include a combination therewith, a tracer, such as, for example, a fluorescent tracer which provides means *for enabling visual indication of the amount of active agent in the device when the device is disposed under the conjunctiva*". (Emphasis added). Suitable fluorescent tracers are then disclosed.

Such disclosure cannot possibly render Appellant's claims obvious. First, the Examiner must provide a reason why one having ordinary skill in the pertinent art would have been led to combine these references so as to arrive at Appellant's claimed invention. There must be something *in the prior art* that suggests the combination other than the hindsight gained from knowledge that the inventor choose to combine these particular things in this particular way. Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). The Examiner has not provided such evidence in this case, and the argument that "all things that go in the eye are the same" is not persuasive. Appellant's invention resides in a punctum plug and not to an energy-activated drug delivery system. It is also well-settled that "obvious to try" is not the standard under §103. In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380, 231 USPQ 81, 90-91 (Fed. Cir. 1986), cert. Denied. 107 S.Ct. 1606 (1987); In re Tomlinson, 363 F.2d 928, 931, 150 USPQ 623, 626 (CCPA 1966); In re O'Farrell, 7 USPQ2d 1673 (Fed. Cir. 1988).

C. Group III - Claim 8.

Claim 8 also stands rejected under 35 USC §103(a) over Sedar et al., U.S. Patent No. 4,959,048, or Freeman, U.S. Patent No. 3,949,750, in view of Gwon et al., U.S. Patent No. 5,178,635. Claim 8 adds to claim 5 the limitation of the radiated light being outside the visible spectrum, and further including a detector for detecting the radiated light. The Board will note from the record that the

Examiner never advanced any substantive argument with respect to the rejection of claim 8. For this reason and the lack of a motivation to combine *prima facie* obviousness has not been established.

Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board's concurrence at this time.

Respectfully submitted,

By:

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Date: Feb. 12, 2004

APPENDIX A**CLAIMS ON APPEAL**

1. A punctum plug which is more easily visualized when positioned within a punctal canal, the plug comprising:
 - a body having an outwardly exposed surface when so positioned; and
 - a substance causing at least the outwardly exposed surface to contrast with surrounding tissue, such that the use of the substance causes the plug to be more easily visualized than if the substance were not present.
2. The punctum plug of claim 1, wherein the substance is disposed on the outwardly exposed surface.
3. The punctum plug of claim 1, wherein the substance is disposed within the plug body.
4. The punctum plug of claim 1, wherein the substance includes an organic or inorganic phosphor, a fluorescent material, reflective beads, quantum dots, a dye or pigment that contrasts with surrounding tissue.
5. The punctum plug of claim 1, wherein the plug is illuminated with light at an illumination wavelength, and wherein the substance generates radiated light at a wavelength other than the illumination wavelength.
6. The punctum plug of claim 5, wherein the illumination wavelength is in the violet or ultraviolet portion of the spectrum.
7. The punctum plug of claim 5, wherein the radiated light is in the visible spectrum.

8. The punctum plug of claim 5, wherein the radiated light is outside the visible spectrum, and further including a detector for detecting the radiated light.